AUG - 4 2011

COVIDIEN

510(K) SUMMARY

1. 510(k) Owner:

Covidien
15 Hampshire Street
Mansfield, MA 02048
Telephone: (508) 261 – 6596
Fax: (508) 261 – 8149

Contact: Mr. Wing Ng
Title: Manager, Regulatory Affairs
Date Prepared: May 6, 2011

2. Device:

Trade Names: Tal Palindrome™ Symmetric Tip Dual Lumen Catheter
Mahurkar® Maxid™ Dual Lumen Catheter
Palindrome™ RT Reverse-Tunneled Catheter
Common Name: Catheter
Classification Name: Implanted Hemodialysis Catheter
Regulation Number: 21 CFR 876.5540
Product Code: MSD
Classification: Class III

3. Predicate Devices:

Tal Palindrome™ Symmetric Tip Dual Lumen Catheter (K043272)
Mahurkar® Maxid™ Dual Lumen Catheter (K002901)
Palindrome™ RT Reverse-Tunneled Catheter (K092205)

4. Device Description:

The Tal Palindrome™ Symmetric Tip Dual Lumen Catheter has a radiopaque shaft with two large inner lumens designed in an opposing "double D" configuration. The proximal end of the catheter features two color-coded luer adapters. The luer adapters are connected to clear extension tubes. Each extension tube contains a clamp and is connected to the catheter hub which contains suture wings. The distal end of the catheter hub is connected to the double lumen catheter shaft. The shaft contains a cuff and extends to a symmetrical distal tip configuration.

The Mahurkar® Maxid™ Dual Lumen Catheter has a 14.5 Fr. radiopaque shaft with two large inner lumens designed in an opposing "double D" configuration. The proximal end of the catheter features two color-coded luer adapters. The luer adapters are connected to clear extension tubes. Each extension tube contains a clamp and is connected to the catheter hub which contains suture wings. The distal end of the catheter hub is connected to the double lumen catheter shaft. The shaft contains a cuff and extends to a staggered distal tip configuration which is available with or without side holes. Configurations with side holes contain five side holes on the arterial lumen and two side holes on the venous lumen.

The Palindrome™ RT Reverse-Tunneled Catheter will be supplied with a detached "proximal end" allowing for the catheter tip to be positioned in the vein first before the catheter shaft is pulled through the patient's subcutaneous tunnel tract in a retrograde fashion. The fully assembled Palindrome™ RT Reverse-

Tunneled Catheter has a 15.0 Fr. radiopaque shaft with two large inner lumens designed in an opposing "double D" configuration. The proximal end of the catheter features two color-coded luer adapters. The luer adapters are connected to clear extension tubes. Each extension tube contains a clamp and is connected to the hub assembly which contains suture wings. The distal end of the catheter hub is connected to the double lumen catheter shaft. The shaft contains a cuff and extends to a symmetrical distal tip configuration.

5. Intended Use:

The Tal Palindrome™ Symmetric Tip Dual Lumen Catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted percutaneously or by cut down. Catheters with greater than 40 cm implant length are indicated for femoral placement.

The Mahurkar® Maxid™ Dual Lumen Catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted percutaneously or by cut down.

The Palindrome™ RT Reverse-Tunneled Catheter is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cut down. Catheters with greater than 40 cm implant length are indicated for femoral insertion.

6. Technological Characteristics:

The modified devices have the same technological characteristics as compared to their respective predicate devices.

7. Performance Data:

Bench top functional testing was completed to support substantial equivalence between the modified device and the current device. The test regimen evaluated the devices' resistance to kink, leak, burst, catheter collapse, fatigue, and the tensile strength at various points of the catheter. The results of the performance testing show that the modified devices continue to meet the relevant product specifications.

Biocompatibility testing per ISO 10993: Biological Evaluation of Medical Devices was completed to support biocompatibility between the modified device and the current device. Material characterization testing was included to show material equivalence where applicable. The results of the biocompatibility testing show that the modified devices continue to be biocompatible for its intended use.

The results of functional testing, biocompatibility testing, and material analytical testing supports the determination of substantial equivalence..

8. Conclusion:

Based on non-clinical testing results, Covidien has demonstrated that the modified chronic catheters are substantially equivalent to their respective existing chronic catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Wing Ng
Manager, Regulatory Affairs
Covidien
Vascular Therapies
15 Hampshire Street
MANSFIELD MA 02048

AUG - 4 2011

Re: K111372
Trade/Device Name: Tal Palindrome™ Symmetric Tip Dual Lumen Catheter
Mahurkar® Maxid™ Dual Lumen Catheter
Palindrome™ RT Reverse-Tunneled Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: July 29, 2011
Received: August 1, 2011

Dear Mr. Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K111372

Section 4
Indications for Use Statement

510(k) Number (if known): ~~To Be Determined~~ K111372

Device Name: Tal Palindrome™ Symmetric Tip Dual Lumen Catheter
Mahurkar® Maxid™ Dual Lumen Catheter
Palindrome™ RT Reverse-Tunneled Catheter

Indications for Use:

The device is indicated for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted percutaneously or by cut down. Catheters with greater than 40 cm implant length are indicated for femoral placement.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111372